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Ty _l	nneth A. Gandy ped/printed name of person signing this certificate perch 5, 2007
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re: patent application of:

Dusan Pavcnik Josef Rösch Frederick Keller

Docket No. : 3006-1658

) Group Art Unit: Serial No. : 09/849,044) 3738

Filed : May 4, 2001

For : ENDOVASCULAR STENT) Examiner:

GRAFT) Alvin J. Stewart

REQUEST FOR PRE-APPEAL BRIEF REVIEW

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

This is a request for a Pre-Appeal Brief Review under the provisions of the Patent and Trademark Office's published rule for the same. The applicants believe that the rejections in this application are clearly deficient, and that they should all be withdrawn. The applicants believe that the reasons stated in their REPLY TO FINAL OFFICE

REQUEST FOR PRE-APPEAL BRIEF REVIEW Serial No. 09/849,044 Group Art Unit 3738 Attorney Docket No. 3006-1658 3006-1658:KAG:#444143 1 of 4

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ACTION filed on September 11, 2006, pages 6-14, are sufficient to overcome all rejections of record. In addition, the applicants provide the following brief summary of the issues.

- 1. According to the Office Action Summary, only claims 1 and 3-9 are pending in the application. However, it is believe that claims 1, 3-9 and 12-18 are pending. Clarification in the next paper is requested.
- 2. In the first sentence on page 2, the Examiner writes "the Examiner has repeated the previous rejection in order to clarify that claims 12-18 are also rejected over the Gregory reference." The basis for this rejection is not stated anywhere in the Office Action. In particular, in the "Claim Rejections 35 USC § 103" portion of the Office Action, no such rejection is made, and no analysis is given. It is noted that this is the second time in sequence that this error has been made. In the REPLY of September 11, 2006, the applicants pointed out that the Examiner's prior Office Action dated July 10, 2006, had the same deficiency. In sum, no rejection of claims 12-18 has yet been made in this prosecution. Examination of claims 12-18 is therefore in order. Further, for the reasons affirmatively offered in the REPLY of September 11, 2006, allowance of claims 12-18 is solicited.
- 3. Claims 1 and 3-9 stand rejected under 35 USC § 103(a) as being unpatentable over Douglas (US Patent 6,090,128) in view of Gregory (US Patent 5,990,379). In making this rejection, the Examiner admits that "Douglas does not disclose a sleeve made of SIS" (small intestine submucosa). To fill this void in the rejection, the Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the Douglas reference with the SIS sleeve of the Gregory reference in order to inhibit the migration of smooth muscle cells in the treated area". In the REPLY of September 11, 2006, and in a prior reply, the applicants pointed out that this characterization of the

Gregory reference as teaching an SIS sleeve appears to be improper as Gregory never says anything about an SIS sleeve. In the present Office Action (and in the previous action) the Examiner does not explain why he believes that the Gregory reference teaches an SIS sleeve and in fact does not challenge the applicants notation that the Gregory reference fails to disclose an SIS sleeve. Instead, the Office Action simply states "regarding the Gregory reference, the Examiner wants to clarify the independent claims don't disclose the use of SIS". However, the Examiner relies upon the Gregory reference's supposed teaching of SIS as the remodelable material of the independent claims. Further, claims 8, 9, 17, and 18 all do require the use of small intestinal submucosa material. It is well established that in order for a rejection under 35 USC § 103 to be proper, combined references must among them teach or suggest all of the elements present in the claims. The Examiner has not provided an explanation of how these two references, even when combined, teach or suggest all of the elements of the present claims, nor do they. For a more detailed review of the reasons that this rejection is in error, the Panel's attention is directed to pages 7-10 of the reply of September 11, 2006.

Additionally as to the above-noted rejection under 35 USC § 103, the Examiner has twice discounted the Declaration of Dr. Michael Hiles submitted on April 3, 2006. The Examiner's stated reason for doing so has been that the Declaration discloses only opinion as to legal conclusion. The legal conclusion at issue is that of obviousness. As explained at pages 12-13 of the September 11, 2006 REPLY, Dr. Hiles does not offer an opinion as to legal conclusion, but rather provides a discussion of technical aspects related to the claimed invention and advantages that can be provided thereby. The Examiner has not expressed any reason to doubt the accuracy of the technical aspects averred by Dr. Hiles, and thus they must be taken into account when considering the claimed invention as a whole. Dr. Hiles' Declaration in this manner further supports that the claimed invention is non-obvious.

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REQUEST FOR PRE-APPEAL BRIEF REVIEW

Review of this case is requested on the basis of the above summary and the records set forth in the prior REPLY of September 11, 2006 and the previously-submitted Declaration of Dr. Michael Hiles. Allowance of this application without further delay is requested.

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Respectfully Submitted,

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